

Claims

What is claimed is:

1. A method of generating an immune response in a subject, comprising mucosally
5 administering to target cells a first replication-defective gene delivery vehicle comprising a polynucleotide encoding at least one first antigen or modified form thereof, said first antigen or modified form thereof being capable of stimulating an immune response in the subject when administered mucosally.
- 10 2. The method of claim 1, wherein the mucosal administration is intranasal.
3. The method of claim 1, wherein the mucosal administration is intrarectal.
4. The method of claim 1, wherein the mucosal administration is intravaginal.
- 15 5. The method of claim 1, wherein the at least one antigen is derived from a sexually transmitted pathogen.
6. The method of claim 5, wherein the sexually transmitted pathogen is a bacteria.
- 20 7. The method of claim 6, wherein the bacteria is selected from the group consisting of gonorrhea, chlamydia and syphilis.
8. The method of claim 5, wherein the sexually transmitted pathogen is a virus.
- 25 9. The method of claim 8, wherein the virus is selected from the group consisting of HIV, HBV, HSV, HCV and HPV.
10. The method of claim 9, wherein the virus is HIV-1.

11. The method of claim 1, wherein the gene delivery vehicle is selected from the group consisting of a nonviral vector, a viral vector, a particulate carrier and a liposome preparation.

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12. The method of claim 11, wherein the gene delivery vehicle is a viral vector selected from the group consisting of a retroviral vector, an adenoviral vector, a poxvirus vector, a picornavirus vector and an alphavirus vector.

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13. The method of claim 12, wherein the alphavirus vector is a Sindbis vector.

14. The method of claim 12, wherein said alphavirus vector is selected from the group consisting of Semliki Forest virus, Venezuelan equine encephalitis virus and Ross River virus vector.

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15. The method of claim 12, wherein said alphavirus vector comprises elements from two or more alphaviruses.

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16. The method of claim 12, wherein the alphavirus vector is delivered to antigen presenting cells.

17. The method of claim 16, wherein the antigen presenting cells are dendritic cells.

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18. The method of claim 1, wherein the target cells are infected *in vivo*.

19. The method of claim 1, wherein the antigen elicits an HLA class I-restricted immune response.

20. The method of claim 19, wherein the antigen further elicits an HLA Class II-restricted immune response.

21. The method of claim 1, including, prior or subsequent to the step of administering to target cells, introducing into target cells a nucleic acid molecule which encodes either Class I or Class II MHC protein, or combinations thereof, or a protein selected from the group consisting of CD3, ICAM-1, LFA-3 or analogues thereof.

22. The method of claim 1, further comprising the step of administering at least one second gene delivery vehicle, said second gene delivery vehicle comprising polynucleotides encoding at least one second antigen or modified form thereof or an immunomodulatory factor.

23. The method of claim 22, wherein the second gene delivery vehicle is administered mucosally.

24. The method of claim 22, wherein the second gene delivery vehicle is administered non-mucosally.

25. The method of claim 1, further comprising the step of administering one or polypeptides to the subject.

26. The method of claim 25, wherein the polypeptides comprise at least one second antigen or modified form thereof.

27. The method of claim 25, wherein the polypeptides comprise an immunomodulatory factor.

28. The method of claim 25, wherein at least one of the polypeptides is administered mucosally.

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